55. The apparatus of claim 54, wherein said hinge allows said coupling apparatus to attain an open configuration for positioning and securing said severed end of said first hollow organ within said input end.

56. The apparatus of claim 54, where said hinge allows said coupling apparatus to attain a closed configuration that substantially engages said severed end of said first hollow organ within said input end.

IN THE DRAWINGS

Applicant has cancelled claims 3, 4, 5, 35, 36, and 37 and therefore, the objection is now moot.

REMARKS

Rejection under 35 U.S.C. 102(e)

The Examiner stated that Claims 3, and 11-15 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Scholz et al [US 6,273,912].

The Applicant asserts that the Scholz et al prior art reference is a graft device that is patently distinguishable from the present invention coupler. Scholz et al provides a graft that inherently has two tissue-to-graft interfaces between the graft and each blood vessel (see Column 1, line 27-29, Scholz et al provides "a polytetrafluoroethylene-tissue interface

between the graft and the blood vessel". The present invention is a tissue-to-tissue coupler, whereby the apparatus is designed to provide mechanical support for a supply tissue interface to engage the receiving tissue interface. It is both clinically important and patentably distinguishable, that the present invention is designed locate the supply and receiving tissue interfaces in close proximity to each other, thereby allowing natural tissue growth between the interfaces. The coupler facilitates the support of the two vessel and their respective interfaces to facilitate a complete natural tissue healing resulting in no artificial interface. Furthermore, once natural tissue growth has sealed the blood supply and receiving supply vessels together, the coupler support function becomes minimized, and it may be desirable to allow the coupler to degrade or become adsorbed.

Scholz et al fails to provide any disclosure, teaching, or embodiment that is designed to locate supply and receiving tissue interfaces in close proximity to each other, thereby allowing a natural tissue growth between and along the supply vessel and receiving vessel interfaces. As stated in Column 1, line 27-29, Scholz et al provides "a polytetrafluoroethylene-tissue interface between the graft and the blood vessel".

Because the Scholz et al invention does not allow for natural tissue growth to seal the supply and receiving vessel interfaces, the graft must remain in place to: 1) restrain blood leakage; and 2) provide adequate support to prevent vessel rupture and separation. Therefore, Scholz et al fails to provide any disclosure, teaching, or embodiment that anticipates the Applicant's present invention.

Additionally, the present invention coupler comprises two halves that are connected by a hinge section. This design facilitates proper placement of the supply vessel within the inside cavity defined between two "clam-shell" halves of the coupler. This allows the clinical practitioner adequate control to precisely align of the supply vessel interface in the orientation necessary for close proximity with the receiving vessel interface when placed in the final position.

The Scholz et al invention does not disclose, claim or teach any apparatus or method of a two half ("clam-shell") design incorporating a hinge mechanism for facilitating proper placement of the supply vessel with the cavity. Therefore, Scholz et al fails to provide any disclosure, teaching, or embodiment that anticipates the Applicant's present invention.

Applicant respectfully asserts that the Examiner has not demonstrated anticipation in accordance with the law. Furthermore, it is submitted that Scholz et al fails to teach a combination of elements necessary to anticipate the Applicants' invention. Thus, Applicants respectfully submit that the amended claim 3, and claims 11-15, which are dependent upon claim 3, are patentably distinct over Scholz et al.

Rejection under 35 U.S.C. 102(b)

The Examiner also stated that Claims 1-10, 17, 23 and 33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Angelchik [US 4,352,358].

The Applicant asserts that the Angelchik prior art reference is a graft device that is both functionally and clinically distinguishable from the present invention. Angelchik provides a deformable graft has "at least two operative modes" which physically change the configuration of the Angelchik device from an introducing shape to an inserted, mounted shape. As stated in column 2, lines 62-68 through column 3, lines 1-7, "the steps of affixing one end of a tubular elastic membrane to a deformed annular member which is shaped and dimensioned when deformed to be inserted through an opening into the body member and is adapted to assume its normal shape after insertion an be retained within the body member around the opening. The annular member is first deformed and then inserted into the opening in the hollow body member with the tubular member expended from the interior to the exterior of the body member. The portion of the member extending through the opening is then radially tensioned to sealingly engage the edges of the opening." The present invention is a tissue-to-tissue coupler, whereby the coupler apparatus is designed to provide mechanical support for a supply tissue interface to a receive tissue interface. The present invention coupler has a "clam-shell" configuration with a hinged section. The present invention "clam-shell" has the capability to become

opened using the hinge section, thereby allowing for accurate placement of a supply vessel and its associated interface within the cavity or lumen of the coupler.

Angelchik fails to provide any disclosure, teaching, or embodiment that is provides for opening a "clam shell" configuration to locate and secure the supply artery. The present invention coupler comprises two halves that are connected by a hinge section. This design facilitates proper placement of the supply vessel within the inside cavity defined between two "clam shell" halves and allows the clinical practitioner adequate control to precisely align of the supply vessel interface in the orientation necessary for close proximity with the receiving vessel interface when placed in the final position. Additionally, there is no means or disclosure that allows the Angelchik device to open or separate in two halves. Rather, as stated in Angelchik column 2, lines 62-68 through column 3, lines 1-7, "the steps of affixing one end of a tubular elastic membrane to a deformed annular member which is shaped and dimensioned when deformed to be inserted through an opening into the body member and is adapted to assume its normal shape after insertion an be retained within the body member around the opening. The annular member is first deformed and then inserted into the opening in the hollow body member with the tubular member expended from the interior to the exterior of the body member. The portion of the member extending through the opening is then radially tensioned to sealingly engage the edges of the opening."

The Angelchik invention does not disclose, claim or teach any methods showing a two half design incorporating a hinge mechanism for facilitating proper placement of the supply vessel within the cavity of the coupler. Therefore, Angelchik fails to provide any disclosure, teaching, or embodiment that anticipates the Applicant's present invention.

Furthermore, it is axiomatic that a portion of the Angelchik device is located within the inside of the receiving vessel as a means of securing the Angelchik device to the supply vessel, as stated in column 3, lines 46-52 "... ring 13 to expand to its full diameter, the annular member 10 is pulled upwardly in the direction of the arrow A to bear against the lower surface of the wall 18 of the body organ and the expansion of the ring 13 radially tensions the tubular membrane 11 causing the membrane 11 to sealingly engage the edges of the opening 17". This is also shown in Figs. 3 and 8. The Applicant asserts that it is clinically undesirable to have a portion protruding into the lumen of a vessel, thereby disrupting the normal flow of blood or other body fluids. The present invention coupler is designed to be secured to the outside surface of the vessel with no significant portion protruding into the vessel lumen.

The Angelchik invention does not disclose, claim or teach any methods showing a two half design incorporating a hinge mechanism that is secured to the outside surface of the receiving vessel. Therefore, Angelchik fails to provide any disclosure, teaching, or embodiment that anticipates the Applicant's present invention.

Applicant respectfully asserts that the Examiner has not demonstrated anticipation in accordance with the law. Furthermore, it is submitted that Angelchik fails to teach a combination of elements necessary to anticipate the Applicants' invention. Thus, Applicants respectfully submit that claims 1-10, 17, 23 and 33 are patentably distinct over Angelchik.

Rejection under 35 U.S.C. 103(a)

The Examiner also stated that Claims 18-22, 24-25, 26-32 and 34-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Angelchik [US 4,352,358].

First, Applicant would like to incorporate the arguments presented above for the patentability of claims 1-10, 17, 23, 33.

The Applicant argues respectfully that the Examiner has not met the burden of establishing a prima facie case of obviousness in accordance with current patent law.

There are several elements necessary to correctly conclude that a claim of obviousness has been established. One of primary elements of establishing a prima facie case of obviousness is that the references require that the resulting combination or modification appear to show or suggest the claimed invention.

As argued above for claims 1-10, 17, 23, 33, the Angelchik invention does not disclose, claim or teach any methods showing a two half design incorporating a hinge mechanism that is secured to the outside surface of the receiving vessel. Therefore, Angelchik fails to provide any disclosure, teaching, or embodiment that anticipates the Applicant's present invention.

Still another element of prima facie obviousness require some reason, suggestion, or motivation from the prior art as a whole for the person of ordinary skill to have combined or modified the references. With respect to the required element, the Federal Circuit has stated that "obviousness cannot be established by combining the teachings or the prior art to produce the claimed invention, absent some teaching suggestion or incentive supporting the combination."

With respect to this required element, the Federal Circuit has stated that "obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching suggestion or incentive supporting the combination." (See *In re* Geiger, 815 F.2d 686, 2 USPQ 2d 1276, 1278 (Fed. Cir. 1987). *See also* Diversitech Corp. v. Centure Steps, Inc., 850 F.2d 675, 678-79, 7 USPQ 2d 1315, 1318 (Fed. Cir. 1988); W.L. Gore & Assocs. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303, 311 (Fed. Cir. 1983):

The Patent Office applies this same standard as explained by the Board, "When the incentive to combine the teachings of the references is not readily apparent, it is the duty of the examiner to explain why combination of the reference teachings is proper... "Absent such reasons or incentives, the teachings of the references are not combindable." (Ex parte Skinner, 2 USPQ 2d 1788, 1790 (B.P.A.I. 1987).

As argued above for claims 1-10, 17, 23, 33, the Angelchik invention does not disclose, claim or teach any methods showing a two half design incorporating a hinge mechanism that is secured to the outside surface of the receiving vessel. Therefore, Angelchik fails to provide any disclosure, teaching, or embodiment that anticipates the Applicant's present invention.

It is therefore asserted by the Applicant the it would not have been obvious to a person of ordinary skill in the art at the time the invention was made to use the Angelchik invention to achieve the present invention coupler.

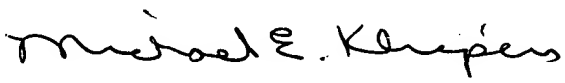
Reconsideration is requested of the rejection of claims 18-22, 24-25, 26-32 and 34-47 as be patentable under 35 U.S.C. '103 in view of the disclosures of Angelchik alone. Angelchik fails to suggest those features of Applicants' invention, as discussed above. Appropriate withdrawal of this 103(a) rejection is therefore requested.

CONCLUSION

In conclusion, Applicants respectfully assert that claims 1-3, 7-34, 38-53, and new claims 54-56 are patentable for the reasons set forth above and that the application is now in condition for allowance. Accordingly, an early notice of allowance is respectfully requested. The Examiner is requested to call the undersigned at (619) 980-8680 for any reason that would advance the instant application to issue.

Dated this eleventh day of February, 2003.

Respectfully submitted,



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